CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

63-165/s-3,s-5,s-6

APPROVAL LETTER

AADA 63-165/S-003, S-005, S-006

Adria Laboratories
Attn: Frederick L. Grab, Ph.D.
P.O. Box 16529
Columbus, OH 43216-6529

JUL 9 1993

Dear Sir:

This is in reference to your supplemental antibiotic drug applications submitted pursuant to Section 314.70 of the Regulations dated March 28, 1991 (S-003 and S-006) and May 23, 1991 (S-005) regarding your abbreviated antibiotic application for Adriamycin PFS™ (Doxorubicin Hydrochloride Injection USP), 2 mg/mL.

Reference is also made to your amendments dated May 11, 1993.

The supplemental applications provide for:

S-003: additional dosage strengths of 75 mg/vial and 100 mg/vial.

S-005: alternate use of a continuous processing vial preparation, filling, capping and rinsing manufacturing line.

S-006: labeling for the new fill sizes.

We have completed the review of these supplemental applications, and they are approved. However, at the time of next printing revise your package insert as described below. Revised labeling may be submitted with an annual report provided you describe the changes.

A. INDICATIONS AND USAGE, first sentence, revise to read -

ADRIAMYCIN PFS® (Doxorubicin HCl Injection USP) has been used...

B. WARNINGS

1. paragraph 2, third sentence -

cumulative [spelling]

2. paragraph 4, third sentence -

...1000/mm^3... [add "/"]

3. paragraph 8, first sentence -

On intravenous administration of doxorubicin, extravasation...
[delete "HCl" and add comma]

C. REFERENCES

1. Revise reference #4 to read -

National Study Commission on Cytotoxic Exposure - Recommendations for Handling Cytotoxic Agents. Available from Louis P. Jeffrey, ScD, Chairman, National Study Commission on Cytotoxic Exposure, Massachusetts College of Pharmacy and Allied Health Sciences, 179 Longwood Avenue, Boston, Massachusetts 02115.

2. Revise reference #7 to read -

American Society of Hospital Pharmacists Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs. Am J Hosp Pharm. 1990:47:1033-1049.

We remind you that you must comply with the requirements for an approved abbreviated antibiotic application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

7/8/93

C. Greg Guyer, Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research